DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

September 3, 2014

Edwards Lifesciences, LLC.
Mr. Andrew S. Mazurkiewicz, Jr., MBA/MKT
Senior Associate, Regulatory Affairs
Critical Care
One Edwards Way, CA 92614

Re: K141495
Trade/Device Names: Pressure Monitoring Kit with TruWave Disposable Pressure Transducers, with list of 577 models attached
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter Tip Pressure Transducer
Regulatory Class: Class II (two)
Product Code: DXO
Dated: August 22, 2014
Received: August 25, 2014

Dear Mr. Mazurkiewicz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

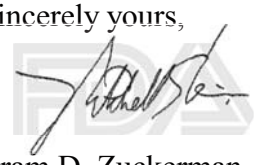
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

SUPPLEMENT TO TABLE 11-2: TRUWAVE MODELS

(Total of 577 models)

Edwards Lifesciences LLC
One Edwards Way · Irvine, CA USA · 92614
Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PX284AN	1	3	210	N/A
PXMK1940	1	3	183	N/A
PX2X2284C	2	3	211	N/A
PXMK2002	1	3	91	N/A
PXMK478	1	3	150	N/A
T494C00B	2	3	180	N/A
PXVMP260	1	3	150	5
PXVP0861	2	3	170	12
T001650A	2	3	150	N/A
VMP426PX	1	3	66	3
PXMK2041	1	3	183	N/A
PXVP2284	1	3	210	12
T001709A	2	3	210	N/A
T432105A	1	30	130	N/A
T322242B	2	3	210	N/A
T531401A	2	3	0	N/A
T434303A	2	3	210	5
T001759A	2	3	171	12
T001737A	2	3	180	5
PX12N	1	30	30	N/A
T001657A	2	3	210	N/A
T001775A	1	3	195	N/A
T433803A	1	3	200	N/A
PX200	1	3	0	N/A
PX1X2	1	3	150	N/A
PXVMP2X31	2	3	160	5
PX600I	1	3	0	N/A
PXMK1849	1	3	193	N/A
T001633A	1	3	150	N/A
T001624A	1	3	150	N/A
T321571A	2	3	165	N/A
PXMK0666	2	3	208	N/A
T001658A	2	3	180	N/A
PX2X2YB	2	3	180	N/A
T391T00A	2	3	221	12
T001712A	2	3	195	N/A
T441T01C	1	3	225	N/A
T491Y01B	1	3	185	N/A
T581203B	1	3	210	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
T530217B	1	3	180	N/A
VMP448PX	1	3	122	3
PXVP2284DZ	1	3	210	12
T001660A	3	3	150	N/A
T100202A	1	3	105	N/A
T001741A	2	3	180	12
PXVP0549	3	3	221	12
PX3X3284C	3	3	211	N/A
PX2X3	2	3	150	N/A
T005002A	1	3	180	N/A
T001745A	1	3	180	12
PX3X3	3	3	150	N/A
PXVK0458	3	3	236	5
PXVMP3X31	3	3	160	5
PX600F	1	3	0	N/A
T005025A	1	3	180	N/A
PX4X4	4	3	211	N/A
PX3X3AN	3	3	211	N/A
PXMK2011	1	3	196	N/A
PXMK9146	2	3	178	N/A
T001789B	1	3	150	N/A
T325202A	1	3	150	N/A
PX3X3272	3	3	178	N/A
PXVMP172	1	3	180	5
PX600F30	1	30	0	N/A
PXMK053	1	3	210	N/A
PXMK2008	1	3	180	N/A
PXVP2284AT3	1	3	210	12
PXVP23X3AT3	3	3	231	12
PXVP2X2AT3	2	3	213	12
PXVK0388	3	3	188	N/A
PXCMK590	2	3	208	N/A
PXVK0387	2	3	188	N/A
PX266C	1	3	168	N/A
PXMK1479	1	3	148	N/A
PXVP2272	1	3	180	12
PX600	1	3	0	N/A
PXMK0695	1	3	130	N/A
PX284	1	3	210	N/A

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Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PX212	1	3	30	N/A
PXMK0976	2	3	147	N/A
PXVK0398	2	3	188	5
PXVMP160	1	3	150	5
PX284R	1	3	210	N/A
PXMK0688	1	30	119	N/A
PX260 (Representative Model)	1	3	150	N/A
PX272	1	3	180	N/A
PX2X2	2	3	150	N/A
PXVMP120	1	3	50	5
PXVP0897	3	3	193	12
PXVP23X3	3	3	170	12
PXVMP184	1	3	210	5
PXVMP272	1	3	180	5
PXVMP284	1	3	210	5
PXVP2260	1	3	150	12
T001631A	1	3	150	N/A
T001645A	1	3	165	N/A
T001670A	1	3	150	5
T001671A	1	3	180	5
T001673A	2	3	150	5
PX3X3MT	3	3	211	N/A
PXMK1876	3	3	213	N/A
PXMK1805	3	3	211	N/A
PXMK2012	4	3	196	N/A
T100209A	1	3	150	N/A
PXAK1568	1	3	0	N/A
PXAK2066	3	3	0	N/A
PXAK2296	4	3	0	N/A
PXMK0933	1	3	208	N/A
PXMK1300	3	3	274	N/A
PXMK1737	2	3	208	N/A
PXMK1863	4	3	178	N/A
PXMK2143	3	3	198	N/A
PXMK2144	3	3	211	N/A
PXMK2258	4	3	183	N/A
PXMK2270	5	3	0	N/A
PXMK560	2	3	30	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXVK0363	3	3	241	5
PXVK0438	4	3	163	5
PXVK0738	4	3	244	5
PXVK0755	3	3	244	5
PXVK0797	3	3	224	5
PXVK0965	3	3	173	5
PXVK1001	3	3	206	5
PXVK1003	4	3	173	5
PXVK1086	3	3	99	5
PXVK268	3	3	203	5
PXVP0686	2	3	220	12
PXVP0812	3	3	155	12
PXVP0880	3	3	231	12
PXVP0902	3	3	206	12
PXVP0966	3	3	231	12
PXVP1066	3	3	177	12
PXVP1087	4	3	199	12
T493Y02B	3	3	195	N/A
T001619A	1	3	30	N/A
T310195A	1	30	150	N/A
T001691A	1	3	171	12
T100214A	1	3	180	N/A
T100215A	1	3	210	N/A
T430023B	2	3	215	12
T001702A	2	3	135	N/A
T001724A	1	3	210	N/A
T001758A	1	3	0	N/A
T001760A	2	3	171	12
T001786A	2	3	195	N/A
T005004A	1	3	150	N/A
T005052A	1	3	210	N/A
T005074A	2	3	175	12
T005080A	1	3	180	N/A
T100212A	1	3	150	N/A
T100500A	1	3	60	5
T100504A	1	3	190	5
T100671B	3	3	171	12
T330639B	2	3	150	N/A
T330831A	1	3	210	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
T330918A	2	3	200	N/A
T330919A	1	3	200	N/A
T330V11A	3	3	200	N/A
T331E02A	1	3	0	N/A
T331F06B	1	3	90	N/A
T331S05B	2	3	200	N/A
T332J01A	1	3	150	N/A
T333529A	2	3	150	N/A
T333709B	2	3	0	N/A
T333710C	2	3	0	N/A
T333918A	2	3	210	N/A
T333919A	1	3	150	N/A
T333C00A	1	3	180	N/A
T333D00A	1	3	150	N/A
T333F00A	1	3	210	N/A
T334041A	2	3	180	N/A
T334402A	2	3	180	N/A
T334708C	1	3	0	N/A
T336546B	2	3	197	12
T336547B	3	3	197	12
T336548B	1	3	197	12
T337003A	1	3	150	N/A
T337119B	2	3	200	N/A
T337305B	3	3	240	N/A
T391T01A	3	3	221	12
T441809C	2	3	150	N/A
T450552C	1	30	156	3
T491U01B	1	3	180	N/A
T492011A	3	3	135	N/A
T493Y03B	1	30	156	N/A
T495009A	3	3	175	N/A
T321570A	1	3	120	N/A
T321572A	3	3	150	N/A
T321573A	1	3	165	N/A
T321575A	1	3	105	N/A
T449103B	2	3	160	5
T100209A	1	3	150	N/A
T391314A	3	3	210	N/A
T770000A	1	3	210	5

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
T005086A	1	3	210	N/A
T440B26B	2	3	200	5
T321811A	1	3	162	5
T321811Z	1	3	162	5
T443422A	2	3	210	N/A
T391312A	1	3	210	N/A
T320161B	1	3	150	N/A
T460061A	1	3	195	N/A
T341211A	1	3	0	N/A
T433202B	1	3	210	N/A
T460225D	3	3	205	N/A
T395705A	1	3	180	N/A
T322241A	1	3	150	N/A
T325615A	1	3	195	N/A
T398807D	1	3	58	12
T531900A	1	3	55	N/A
T341210A	1	3	150	N/A
T397705B	2	3	180	N/A
T433802A	1	3	220	5
T320943A	2	3	120	N/A
T320940B	3	3	120	N/A
PXVJ0441	1	30	168	3
T005094A	1	3	150	N/A
T430181A	1	3	221	5
PX601	1	3	0	N/A
T395606B	3	3	180	N/A
T451703A	3	3	215	12
T451703A	3	3	215	12
T433806A	2	3	220	5
T310682A	3	3	150	N/A
T432703A	2	3	220	5
T349302A	1	30	150	N/A
T530317A	1	3	30	N/A
T413405A	1	3	150	N/A
T431305A	3	3	190	5
T320162C	2	3	60	N/A
T349301B	1	3	180	N/A
T328500A	1	3	180	N/A
PXMK0010	1	3	230	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXMK0011	2	3	230	N/A
PXMK0012	3	3	230	N/A
PXMK0013	1	3	0	N/A
PXMK0014	1	3	150	N/A
T610002A	1	3	30	N/A
PXMK2329	2	3	89	N/A
PXMK2330	3	3	119	N/A
T413675A	2	3	225	N/A
T397704A	1	3	180	N/A
T001725A	1	3	150	N/A
T322238A	1	3	190	N/A
T322515A	3	3	180	N/A
T398603A	2	3	220	5
T001744A	1	3	220	5
T323922D	2	3	180	N/A
T434304A	1	3	190	5
T433204B	1	3	210	N/A
PX24N	1	30	60	N/A
T323923A	1	3	30	N/A
T433801A	1	3	200	N/A
T430142A	4	3	150	N/A
T312306A	1	3	15	N/A
T005048B	1	3	200	5
T320563A	1	3	200	N/A
T530310A	1	3	150	N/A
T391313A	2	3	210	N/A
T323924C	1	3	210	N/A
T341212A	1	3	90	N/A
T320137D	3	3	150	N/A
T443952B	2	3	136	3
T325306B	1	3	210	N/A
T413670A	1	3	180	N/A
T413406A	1	3	150	N/A
T410001Z	1	3	165	N/A
T432104B	2	3	250	5
T450217A	2	3	190	N/A
T450217A	2	3	190	N/A
T440B28A	1	3	200	5
T320544A	1	3	0	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
T440B21A	2	3	30	N/A
T434500B	1	3	225	5
T001767A	1	3	150	N/A
T323932C	2	3	180	N/A
T323931C	3	3	180	N/A
T005050B	3	3	200	5
T433201A	2	3	150	N/A
T328201A	1	3	180	N/A
T530116B	3	3	0	N/A
T322256A	3	3	240	N/A
T398105B	2	3	180	N/A
T397708A	1	3	191	12
T322247A	1	3	150	N/A
T310761C	1	3	0	N/A
T320941A	1	3	120	N/A
T433804Z	1	3	210	5
T450553A	3	3	186	3
T451702A	2	3	215	12
T001743A	1	3	160	5
T430609A	3	30	150	N/A
T001765A	1	3	186	12
T322244A	1	3	60	N/A
T432618G	1	3	215	12
T005049B	2	3	200	5
T530219D	2	3	165	12
T310762A	1	3	90	N/A
T447907A	2	3	150	N/A
T581201F	3	3	200	N/A
T320564A	1	30	180	N/A
T320947B	1	3	0	N/A
T310197A	1	30	150	N/A
T398808A	1	3	231	12
T430169A	1	3	180	3
T410115C	3	3	150	N/A
T005005A	1	3	180	N/A
T430139A	1	3	150	N/A
T441L01A	2	3	300	N/A
T450545A	3	3	190	5
T530219A	2	3	180	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
T430180A	2	3	220	5
T410114B	2	3	150	N/A
T001797B	1	3	150	N/A
T431514C	2	3	210	N/A
T413403C	1	3	150	N/A
T430179A	3	3	220	5
T450544A	2	3	190	5
T431108A	1	3	265	12
T001746A	3	3	190	5
T440B20B	2	3	200	N/A
T326207B	1	3	171	12
T430178B	3	3	190	5
T430168A	1	30	180	3
T434501B	2	3	225	5
T460237A	2	3	195	N/A
T413642B	1	3	150	N/A
T430177B	1	3	30	N/A
T001713A	2	3	180	N/A
T770003A	3	3	200	5
T460243A	3	3	175	12
T430140A	3	3	190	5
T322251A	2	3	150	N/A
T320139D	1	30	0	N/A
T530223A	1	3	165	12
T391608B	1	3	30	N/A
T770001A	4	3	220	5
T770002A	2	3	200	5
T470411B	1	30	25	3
T323930D	2	3	150	N/A
T461803B	1	3	160	N/A
T434502B	3	3	225	5
T460250A	1	30	140	N/A
T005093A	2	3	150	N/A
T460235A	1	3	135	N/A
PXMK2294	1	3	211	N/A
T460249A	1	30	140	N/A
T492F02B	1	3	160	5
T492F02Z	1	3	160	5
PXVK282	3	3	193	5

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Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXMK1392	1	30	120	N/A
T270003B	2	3	0	N/A
PXMK2217	3	3	211	N/A
VMP406PX	1	3	15	3
PXMK1267	2	3	0	N/A
PXMK1589	1	3	0	N/A
PXMK2274	1	3	30	N/A
T001691M	1	3	215	12
T001741M	2	3	235	5
T001744M	1	3	235	5
T005025M	1	3	180	N/A
T005050M	3	3	235	5
T100671M	3	3	215	12
T430023M	2	3	215	12
T470411M	1	30	32	3
T270004B	2	3	0	N/A
T270900A	2	3	210	N/A
PXVJ356	1	3	120	3
PXMK2210	3	3	211	N/A
PXMK188	1	30	60	N/A
PXMK2122	1	30	60	N/A
VMP306PX	1	30	15	3
PXAVMP3	2	3	173	5
PX604	1	3	0	N/A
PXMK2277	1	3	0	N/A
PXVMP2X21	2	3	160	5
PXMK2016	1	3	168	N/A
PXMK1077	1	3	150	N/A
PX36N	1	30	90	N/A
PXMK2056	1	3	240	N/A
PXMK2137	3	3	211	N/A
PXMK1780	1	3	30	N/A
PXMK1140	3	3	208	N/A
PXMK2042	2	3	180	N/A
PXMK1691	1	3	210	N/A
PXVK0670	1	3	191	5
PXMK1476	2	3	178	N/A
PXMK0692	1	30	15	N/A
PXMK0774	1	30	60	N/A

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Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXMK1915	1	30	90	N/A
PXMK1393	3	3	180	N/A
PXMK1997	1	30	173	N/A
PXMK1714	4	3	241	N/A
PXMK1716	2	3	211	N/A
PXMK2009	1	3	180	N/A
PXMK2010	1	3	180	N/A
PXMK1299	1	3	269	N/A
PXMK1360	3	3	147	N/A
PXVK0437	3	3	218	N/A
PXVK0478	1	3	147	N/A
PXMK2108	2	3	213	N/A
PXMK1749	3	3	213	N/A
PXMK1750	4	3	213	N/A
PXMK1696	2	3	0	N/A
T001718A	2	3	210	N/A
T440907B	3	3	210	N/A
PXMK1977	1	3	150	N/A
PXMK2036	2	3	211	N/A
PXVJ0690	1	3	254	3
PXVK1079	3	3	203	5
T001724A	1	3	210	N/A
T005004A	1	3	150	N/A
PXMK2279	3	3	208	N/A
PXMK2284	1	3	60	N/A
PXMK2298	2	3	178	N/A
PXMK2302	1	3	150	N/A
PXMK2306	1	3	210	N/A
PXMK2307	2	3	208	N/A
PXMK2308	2	3	150	N/A
PXMK2316	1	3	0	N/A
PXMK2321	1	3	120	N/A
PXMK2327	1	3	30	N/A
PXMK2047	1	30	15	N/A
PXMK7729	1	30	30	N/A
PXMK2331	4	3	30	N/A
PXMK273	1	3	150	N/A
PXMK287	1	3	150	N/A
PXMK318	3	3	206	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXMK332	1	3	76	N/A
PXMK500	1	3	210	N/A
PXMK573	1	3	180	N/A
PXMK575	3	3	274	N/A
PXMK582	1	3	150	N/A
PXVJ0705	1	3	18	3
PXVK0364	1	3	241	5
PXVK0386	1	3	188	N/A
PXVK0412	1	3	198	5
PXVK0467	1	3	224	5
PXVK0481	4	3	190	5
PXVK064	1	3	190	5
PXVK0789	1	3	210	N/A
PXVK0796	1	3	224	5
PXVK0802	1	3	213	5
PXVK0853	3	3	193	5
PXVK093	1	3	206	5
PXVK0996	1	3	174	5
PXVK1041	3	3	254	5
PXVK1075	1	3	193	N/A
PXVK1076	2	3	218	N/A
PXVK1084	3	3	193	5
PXVK1085	3	3	203	5
PXVK1091	4	3	210	N/A
PXVK1099	1	3	157	N/A
PXVK1102	1	3	132	N/A
PXVK1103	3	3	203	5
PXVK220	2	3	170	5
PXVK225	2	3	175	5
PXVK275	2	3	168	5
PXVJ0711	1	30	132	3
PXVK2W4IV	2	3	198	5
PXVMP172AT3	1	3	224	5
PXVMP2X22	2	3	160	5
PXVMP3X32	3	3	193	5
PXVP0550	3	3	231	12
PXVP0566	1	3	208	12
PXVP0765	2	3	193	12
PXVP0778	1	3	230	12

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXVP0843	2	3	201	12
PXVP1071	3	3	221	12
PXVP1072	2	3	221	12
PXVP1073	1	3	221	12
PXVP1089	2	3	170	12
PXVP1097	3	3	170	12
PXVP1098	1	3	170	12
PXVP1107	2	3	231	12
PXVP3X3DZ	3	3	170	12
PXMK0940	1	30	30	N/A
PX278C	1	3	198	N/A
PX602	1	3	0	N/A
PX604I	1	3	0	N/A
PX604INS	1	3	NA	N/A
PXAK0712	1	3	0	N/A
PXAK0910	1	3	0	N/A
PXAK1022	1	3	0	N/A
PXAK1639	1	3	76	N/A
PXAK1898	1	3	0	N/A
PXAK2253	1	3	0	N/A
PXAK2422	1	3	0	N/A
PXAVMP	1	3	172	5
PXCMK315	1	3	148	N/A
PXMK0619	1	3	180	N/A
PXMK0657	2	3	150	N/A
PXMK0658	1	3	150	N/A
PXMK0769	1	3	46	N/A
PXMK077	1	3	120	N/A
PXMK0854	1	3	150	N/A
PXMK0882	1	3	180	N/A
PXMK0973	1	3	178	N/A
PXMK099	1	3	0	N/A
PXMK1063	1	3	240	N/A
PXMK1065	3	3	239	N/A
PXMK1070	1	3	120	N/A
PXMK1071	2	3	119	N/A
PXMK1074	2	3	180	N/A
PXMK1085	1	3	180	N/A
PXMK1132	4	3	206	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXMK1159	1	3	0	N/A
PXMK1161	1	3	208	N/A
PXMK1183	1	3	180	N/A
PXMK1256NS	1	3	NA	N/A
PXMK1289	1	3	0	N/A
PXMK1302	1	3	120	N/A
PXMK1326	1	3	30	N/A
PXMK1350	1	3	210	N/A
PXMK1389	2	3	150	N/A
PXMK1390	3	3	150	N/A
PXMK142	1	3	90	N/A
PXMK1505	1	3	0	N/A
PXMK1506	1	3	0	N/A
PXMK1545	1	3	119	N/A
PXMK1577	1	3	23	N/A
PXMK1640	4	3	274	N/A
PXMK1717	2	3	58	N/A
PXMK1724	4	3	0	N/A
PXMK1736	2	3	234	N/A
PXMK1752	1	3	120	N/A
PXMK1761	3	3	119	N/A
PXMK1861	1	3	180	N/A
PXMK1882	1	3	30	N/A
PXMK1903	1	3	89	N/A
PXMK1927	4	3	119	N/A
PXMK1935	1	3	90	N/A
PXMK1939	1	3	150	N/A
PXMK1967	4	3	196	N/A
PXMK1970	3	3	150	N/A
PXMK1978	2	3	150	N/A
PXMK2005	1	3	15	N/A
PXMK2024	1	3	198	N/A
PXMK2064	1	3	180	N/A
PXMK2065	3	3	183	N/A
PXMK2082	3	3	203	N/A
PXMK2112	1	3	210	N/A
PXMK2127	3	3	180	N/A
PXMK2138	1	3	30	N/A
PXMK2147	1	3	0	N/A

Supplement to Table 11-2: TruWave™ Models				
Model #	**# of Transducers (P/N 500479)**	**Transducer Flow Rate (mL/hr)**	**Tubing Length (cm)**	**Blood Sampling Reservoir Size (cc) VAMP (K896819)**
PXMK2043	3	3	183	N/A
PXMK2153	2	3	183	N/A
PXMK2160	1	3	0	N/A
PXMK2164	3	3	150	N/A
PXMK2221	1	3	150	N/A
PXMK2222	1	3	210	N/A
PXMK2242	1	3	30	N/A
PXMK2255	1	3	150	N/A
PXMK2256	1	3	183	N/A
PXMK2259	1	3	150	N/A
PXMK2260	1	3	150	N/A
PXMK2267	1	3	180	N/A
PXMK2273	1	3	120	N/A
PXMK2225	2	3	180	N/A
PXMK1964	1	3	163	N/A
PXMK1965	1	3	132	N/A
PXMK1976	2	3	210	N/A
T310845A	1	30	171	3

SECTION 4 - INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number (if known): **K141495**

Device Name: TruWave™ Disposable Pressure Transducer

Indications For Use:

The Pressure Monitoring Kit with TruWave Disposable Pressure Transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.

Prescription Use _X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5 – 510(k) SUMMARY

TruWave™ Disposable Pressure Transducer 510(k)	
510(k) Submitter	Edwards Lifesciences, LLC
Contact Person	Andrew S. Mazurkiewicz, Jr., MBA/MKT Edwards Lifesciences One Edwards Way Irvine, CA 92614 Tel: (949) 250-5167
Date Prepared	June 5, 2014
Trade Name	TruWave™
Common Name	Disposable Pressure Transducer
Classification Name	Transducer, pressure, catheter tip
Regulation Class/Product Code	21 CFR 870.2870 Class II DXO
Predicate Device(s)	K925638 - Phoenix Disposable Pressure Transducer #73-600 (Cleared 10/18/1993)
Device Description	The Edwards Lifesciences Pressure Monitoring Kit with TruWave disposable pressure transducer is a sterile, single-use kit that monitors intravascular blood pressure, intracranial pressure, and intrauterine pressure. The disposable sterile cable (available in 12-inch/30 cm and 48-inch/120 cm lengths) interfaces exclusively with an Edwards Lifesciences cable that is specifically wired for the patient monitor used to display the pressure data. The TruWave Disposable Pressure Transducer has a straight, flow-through design, where the fluid is passed across the pressure sensor. The DPT is available either with or without an integral flush device.
Indications for Use/Intended Use	The Pressure Monitoring Kit with TruWave Disposable Pressure Transducer is for use on patients requiring intravascular, intracranial, or intrauterine pressure monitoring.

Comparative Analysis	Material biocompatibility testing in compliance with applicable ISO 10993 requirements, and performance testing was conducted to compare the proposed device to the predicate device. The results of the testing indicate that the fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate). The proposed change to the TruWave disposable pressure transducer has been shown to be safe, effective, and substantially equivalent to the predicate device (Phoenix [TruWave] disposable pressure transducer) for its intended use in hospitals and other appropriate clinical environments.
Functional/ Safety Testing	The TruWave disposable pressure transducer has successfully passed functional- performance testing and biocompatibility testing, in accordance with applicable consensus standards.
Conclusion	The TruWave disposable pressure transducers has been shown to be safe, effective, and substantially equivalent to the predicate device (Phoenix [TruWave] disposable pressure transducer) for its intended use in hospitals and other appropriate clinical environments.